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\*Practice Limited to  
Federal Agencies

March 16, 2007

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Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

**Art Unit 1618**

**Attn: Mail Stop Amendment**

Re: U.S. Utility Patent Application  
Application No. 10/565,885; Filed: January 25, 2006  
For: **Administration of Anti-Cytokine F(ab')<sub>2</sub> Antibody Fragments**  
Inventors: LOPEZ DE SILANES *et al.*  
Our Ref: 2399.0080000/JAG/LAV

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Information Disclosure Statement Under 37 C.F.R. § 1.97(b);
2. Form PTO/SB/08A (1 sheet) listing twenty-three (23) documents (US1-US20 and FP1-FP3);
3. Form PTO/SB/08B (4 sheets) listing thirty-five (35) documents (NPL1-NPL35);
4. Copies of thirty-eight (38) cited documents (FP1-FP3 and NPL1-NPL35); and
5. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier.

In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents

March 16, 2007

Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in black ink, reading "Laura Vogel". The signature is fluid and cursive, with the first name "Laura" and the last name "Vogel" clearly distinguishable.

Laura A. Vogel  
Attorney for Applicants  
Registration No. 55,702

LAV/U-W:trh:amr  
Enclosures

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

LOPEZ DE SILANES *et al.*

Appl. No.: 10/565,885

Filed: January 25, 2006

For: **Administration of Anti-Cytokine  
F(ab')<sub>2</sub> Antibody Fragments**

Confirmation No.: 8053

Art Unit: 1618

Examiner: *To Be Assigned*

Atty. Docket: 2399.0080000/JAG/LAV

**Information Disclosure Statement Under 37 C.F.R. § 1.97(b)**

***Mail Stop Amendment***

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying IDS Forms, PTO/SB/08A and PTO/SB/08B, are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Copies of documents **FP1** to **FP3** and **NPL1** to **NPL35** are submitted herewith. However, in accordance with 37 C.F.R. § 1.98(a)(2), copies of U.S. patents and patent application publications, **US1** to **US20**, cited on the attached IDS Form, PTO/SB/08A, are not submitted.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following discussion of the relevance of the non-English language document **NPL18** cited on Form PTO/SB/08B:

Document **NPL18**, Maraboto Martinez, J.A., *et al.*, "Panorama Epidemiológico de las Intoxicaciones Causadas por Animales Ponzofiosos en la Población Derechohabiente del IMSS 1990-1998," in *3<sup>a</sup> Reunión de Expertos en Envenenamiento*

*por Animales Ponzoñosos*, Instituto de Biotecnología, Universidad Nacional Autónoma de México, Alcapulco, Gro., México (February 17-19, 1999), is in the Spanish language. An English language translation of document NPL18 is attached as **NPL19**.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

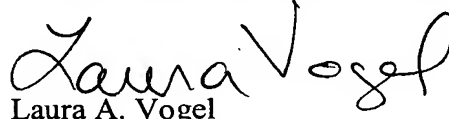
This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

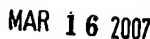


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Approved for use through 03/31/2007. OMB 0651-0031

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Subsidiary form 1449/PTO

*(Use as many sheets as necessary)*

Sheet	1	of	1
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**Complete if Known**

Application Number	10/565,885
Filing Date	January 25, 2006
First Named Inventor	LOPEZ DE SILANES, Juan
Art Unit	1618
Examiner Name	<i>To Be Assigned</i>
Attorney Docket Number	2399.0080000/JAG/LAV

## U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (If Known)			
	US1	4,806,346	02/21/1989	Hum <i>et al.</i>	
	US2	4,814,433	03/21/1989	Fredrickson	
	US3	4,849,352	07/18/1989	Sullivan <i>et al.</i>	
	US4	4,940,670	07/10/1990	Rhodes	
	US5	5,328,834	07/12/1994	Ngo <i>et al.</i>	
	US6	5,443,976	08/22/1995	Carroll	
	US7	5,733,742	03/31/1998	Landon	
	US8	5,888,511	03/30/1999	Skurkovich <i>et al.</i>	
	US9	5,904,922	05/18/1999	Carroll	
	US10	6,333,032	12/25/2001	Skurkovich <i>et al.</i>	
	US11	6,448,054	09/10/2002	Poznansky <i>et al.</i>	
	US12	6,534,059	03/18/2003	Skurkovich <i>et al.</i>	
	US13	6,709,655	03/23/2004	Lopez de Silanes <i>et al.</i>	
	US14	2003/0049725 A1	03/13/2003	Heavner <i>et al.</i>	
	US15	2003/0215448 A1	11/20/2003	Skurkovich <i>et al.</i>	
	US16	2003/0223995 A1	12/04/2003	Skurkovich <i>et al.</i>	
	US17	2003/0224005 A1	12/04/2003	Skurkovich <i>et al.</i>	
	US18	2003/0228310 A1	12/11/2003	Skurkovich <i>et al.</i>	
	US19	2004/0062768 A1	04/01/2004	Skurkovich <i>et al.</i>	
	US20	2004/0086508 A1	05/06/2004	Skurkovich <i>et al.</i>	

## FOREIGN PATENT DOCUMENTS

[illegible]

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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/565,885
				Filing Date	January 25, 2006
				First Named Inventor	LOPEZ DE SILANES, Juan
				Art Unit	1618
				Examiner Name	To Be Assigned
Sheet	1	of	4	Attorney Docket Number	2399.0080000/JAG/LAV

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	NPL1	BECERRIL, B., <i>et al.</i> , "Cloning and characterization of cDNAs that code for Na <sup>+</sup> - channel-blocking toxins of the scorpion <i>Centruroides noxius</i> Hoffman," <i>Gene</i> 128:165-171, Elsevier Science Publishers B.V. (1993)	
	NPL2	CAIN, B.S., <i>et al.</i> , "The Physiologic Basis for Anticytokine Clinical Trials in the Treatment of Sepsis," <i>J. Am. Coll. Surg.</i> 186:337-351, American College of Surgeons (1998)	
	NPL3	CALDERON-ARANDA, E.S., <i>et al.</i> , "Neutralizing Capacity of Murine Sera Induced by Different Antigens of Scorpion Venom," <i>Toxicon</i> 31:327-337, Pergamon Press Ltd. (1993)	
	NPL4	CALDERON-ARANDA, E.S., <i>et al.</i> , "The use of synthetic peptides can be a misleading approach to generate vaccines against scorpion toxins," <i>Vaccine</i> 13:1198-1206, Elsevier Science, Ltd. (1995)	
	NPL5	COURAUD, F., <i>et al.</i> , "Two Types of Scorpion Toxin Receptor Sites, One Related to the Activation, the Other to the Inactivation of the Action Potential Sodium Channel," <i>Toxicon</i> 20:9-16, Pergamon Press Ltd. (1982)	
	NPL6	DEHESA-DÁVILA, M. and Possani, L.D., "Scorpionism and Serotherapy in Mexico," <i>Toxicon</i> 32:1015-1018, Elsevier Science Ltd. (1994)	
	NPL7	DEHESA-DÁVILA, M., <i>et al.</i> , "Clinical Toxicology of Scorpion Stings," in <i>Handbook of Clinical Toxicology of Animal Venoms and Poisons</i> , Ch. 18, Meier, J., and White, J., eds., CRC Press, Boca Raton, FL, pp. 221-238 (1995)	
	NPL8	Abstract of DICK, A.D., <i>et al.</i> , "Neutralizing TNF-alpha Activity Modulates T-cell Phenotype and Function in Experimental Autoimmune Uveoretinitis," <i>J. Autoimmun.</i> 11:255-264 (1998)	
	NPL9	EDMAN, P. and Begg, G., "A Protein Sequenator," <i>Eur. J. Biochem.</i> 1:80-91, Blackwell Science, Ltd. on behalf of the Federation of European Biochemical Societies (1967)	
	NPL10	FEKADE, D., <i>et al.</i> , "Prevention of Jarisch-Herxheimer Reactions by Treatment with Antibodies Against Tumor Necrosis Factor $\alpha$ ," <i>N. Engl. J. Med.</i> 335:311-315, Massachusetts Medical Society (1996)	

Examiner Signature		Date Considered	
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				Filing Date	January 25, 2006
				First Named Inventor	LOPEZ DE SILANES, Juan
				Art Unit	1618
				Examiner Name	To Be Assigned
Sheet	2	of	4	Attorney Docket Number	2399.0080000/JAG/LAV

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T <sup>2</sup>
	NPL11	FOX, D.A., "Cytokine Blockade as a New Strategy to Treat Rheumatoid Arthritis," <i>Arch. Intern. Med.</i> 160:437-444, American Medical Association (2000)	
	NPL12	GARCÍA, C., <i>et al.</i> , "Isolation, Characterization and Comparison of Novel Crustacean Toxin with a Mammalian Toxin from the Venom of the Scorpion <i>Centruroides noxius</i> Hoffman," <i>Comp. Biochem. Physiol.</i> 116B:315-322, Elsevier Science, Inc. (1997)	
	NPL13	KRUEGER, J.G., "The immunologic basis for the treatment of psoriasis with new biologic agents," <i>J. Am. Acad. Dermatol.</i> 46:1-23, American Academy of Dermatology, Inc. (January 2002)	
	NPL14	LEGROS, C., <i>et al.</i> , "Use of fusion protein constructs to generate potent immunotherapy and protection against scorpion toxins," <i>Vaccine</i> 20:934-942, Elsevier Science, Ltd. (2002)	
	NPL15	LICEA, A.F., <i>et al.</i> , "FAB Fragments of the Monoclonal Antibody BCF2 are Capable of Neutralizing the Whole Venom from the Scorpion <i>Centruroides noxius</i> Hoffman," <i>Toxicon</i> 34:843-847, Elsevier Science Ltd. (1996)	
	NPL16	LISMAN, K.A., <i>et al.</i> , "Managing Heart Failure with Immunomodulatory Agents," <i>Cardiol. Clin.</i> 19:617-625, W.B. Saunders Co. (2001)	
	NPL17	LUGER, T., "Treatment of immune-mediated skin diseases: future perspectives," <i>Eur. J. Dermatol.</i> 11:343-347, accessed at <a href="http://www.john-libbey-eurotext.fr/en/revues/medecine/ejd/e-docs/00/01/88/A6/article.md">http://www.john-libbey-eurotext.fr/en/revues/medecine/ejd/e-docs/00/01/88/A6/article.md</a> , John Libbey Eurotext (2001)	
	NPL18	MARABOTO MARTINEZ, J.A., <i>et al.</i> , "Panorama Epidemiológico de las Intoxicaciones Causadas por Animales Ponzosofos en la Población Derechohabiente del IMSS 1990-1998," in 3 <sup>a</sup> <i>Reunión de Expertos en Envenenamiento por Animales Ponzosofos</i> , Instituto de Biotecnología, Universidad Nacional Autónoma de México, Alcapulco, Gro., México (February 17-19, 1999)	
	NPL19	English translation of Maraboto Martinez, J.A., <i>et al.</i> , "Panorama Epidemiológico de las Intoxicaciones Causadas por Animales Ponzosofos en la Población Derechohabiente del IMSS 1990-1998," in 3 <sup>a</sup> <i>Reunión de Expertos en Envenenamiento por Animales Ponzosofos</i> , Instituto de Biotecnología, Universidad Nacional Autónoma de México, Alcapulco, Gro., México (February 17-19, 1999)	
	NPL20	MARTIN, G.S., "Current Management Strategies for Severe Sepsis and Septic Shock," Presented at Chest 2001: 67th Annual Scientific Assembly of the American College of Chest Physicians, November 4-8, 2001, Philadelphia, PA, accessed online at <a href="http://www.medscape.com/viewarticle/412927">http://www.medscape.com/viewarticle/412927</a> , Medscape Portals, Inc., 4 pages (2001)	

Examiner Signature	Date Considered
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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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NON PATENT LITERATURE DOCUMENTS			
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	NPL21	NONNER, W., "Effects of <i>Leiurus</i> Scorpion Venom on the "Gating" Current in Myelinated Nerve," <i>Adv. Cytopharmacol.</i> 3:345-352, Raven Press (1979)	
	NPL22	POSSANI, L.D., <i>et al.</i> , "Scorpion toxins from <i>Centruroides noxius</i> and <i>Tityus serrulatus</i> ," <i>Biochem. J.</i> 229:739-750, Biochemical Society/Portland Press (1985)	
	NPL23	POSSANI, L.D., <i>et al.</i> , "Scorpion toxins specific for NA <sup>+</sup> -channels," <i>Eur. J. Biochem.</i> 264:287-300, Blackwell Science, Ltd. on behalf of the Federation of European Biochemical Societies (1999)	
	NPL24	POSSANI, L.D., <i>et al.</i> , "Peptides and genes coding for scorpion toxins that affect ion-channels," <i>Biochimie</i> 82:861-868, Editions Scientifiques Elsevier (2000)	
	NPL25	PRESENT, D.H., <i>et al.</i> , "Infliximab for the Treatment of Fistulas in Patients with Crohn's Disease," <i>N. Engl. J. Med.</i> 340:1398-1405, Massachusetts Medical Society (1999)	
	NPL26	QIAN, Y., <i>et al.</i> , "Topical Soluble Tumor Necrosis Factor Receptor Type I Suppresses Ocular Chemokine Gene Expression and Rejection of Allogenic Corneal Transplants," <i>Arch. Ophthalmol.</i> 118:1666-1671, American Medical Association (2000)	
	NPL27	STAPCZYNSKI, J.S., "Shock, Septic," Dire, D.J., <i>et al.</i> , eds., eMedicine.com Inc., accessed online at <a href="http://emedicine.com/EMERG/topic533.htm">http://emedicine.com/EMERG/topic533.htm</a> , eMedicine.com, Inc., 25 pages (2004)	
	NPL28	STRICHARTZ, G., <i>et al.</i> , "An Integrated View of the Molecular Toxinology of Sodium Channel Gating in Excitable Cells," <i>Ann. Rev. Neurosci.</i> 10:237-267, Annual Reviews, Inc. (1987)	
	NPL29	TORRES, P.F., and KIJLSTRA, A., "The role of cytokines in corneal immunopathology," <i>Ocul. Immunol. Inflamm.</i> 9:9-24, Swets & Zeitlinger (2001)	
	NPL30	ZAMUDIO, F., <i>et al.</i> , "Amino acid sequence and immunological characterization with monoclonal antibodies of two toxins from the venom of the scorpion <i>Centruroides noxius</i> Hoffman," <i>Eur. J. Biochem.</i> 204:281-292, Blackwell Science, Ltd. on behalf of the Federation of European Biochemical Societies (1992)	

Examiner Signature		Date Considered	
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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE  STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/565,885
				Filing Date	January 25, 2006
				First Named Inventor	LOPEZ DE SILANES, Juan
				Art Unit	1618
				Examiner Name	To Be Assigned
Sheet	4	of	4	Attorney Docket Number	2399.0080000/JAG/LAV

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	NPL31	ZHU, S., <i>et al.</i> , "Early Expression of Proinflammatory Cytokines Interleukin-1 and Tumor Necrosis Factor- $\alpha$ after Corneal Transplantation," <i>J. Interferon. Cytokine. Res.</i> 19:661-669, Mary Ann Liebert, Inc. (1999)	
	NPL32	International Search Report for International Patent Application No. PCT/MX02/00013, European Patent Office, Netherlands, mailed on August 16, 2002	
	NPL33	Dialog File 351, Accession No. 9271133, Derwent WPI English language abstract for Spanish Patent No. 2 106 183 (Document FP1)	
	NPL34	English language translation of Secretaría de Salud, "Pyrogen Tests," in: <i>Farmacopea de los Estados Unidos Mexicanos</i> , Vol. I, Secretaría de Salud, Mexico City, MX, pp. 334-335 (2000)	
	NPL35	English language translation of Secretaría de Salud, "Potency of Anti-Poison Sera," in <i>Farmacopea de los Estados Unidos Mexicanos</i> , Vol. II, Secretaría de Salud, Mexico City, MX, pp. 1756-1757 (2000)	

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Examiner Signature		Date Considered	
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